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How much pain reduction is clinically relevant in low back pain patients undergoing chiropractic treatment? A secondary analysis from a prospective cohort outcomes study.

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Inhaltsverzeichnis

1. Abstract

Objective: There is inconsistency and controversy in quantifying how much reduction in pain is clinically meaningful for low back pain patients undergoing various treatments. In the present study we analyzed the association between pain reduction on the 'Numeric Rating Scale' for pain (NRS) and a clinically significant improvement at various treatment outcome time points in low back pain patients who have undergone chiropractic treatment. The purposes were to determine absolute and percentage pain reduction values that are associated with clinically relevant improvement in these patients and to compare the results of acute and chronic patients.

Methods: Data from 895 patients with low back pain were collected. Forty-four Doctors of Chiropractic practicing in different parts of Switzerland contributed to the data gathering between May 2010 and May 2014. Before treatment, patients filled out forms including the NRS, the Oswestry disability index questionnaire (ODI) and the 'Patients Global Impression of Change' scale (PGIC). Follow-up data collection was completed 1 Week, 1 month and 3 months after the first treatment by using short telephone interviews executed by trained research assistants. The changes of the NRS scores from baseline were calculated using the Wilcoxon test for matched pairs. To compare absolute and percentage NRS score changes between 'improved' and 'not improved' patients, the unpaired Student's t-test was used. A one-way ANOVA was done to compare the scores between acute and chronic patients and the χ^2 test was used to calculate the proportions of acute and chronic patients regarding 'improvement'.

Results: Absolute and percentage pain reduction values on the NRS associated with 'improvement' on the PGIC scale differed significantly between acute and chronic patients and changed significantly depending on the assessment time point. Acute patients always showed significantly higher reduction values associated with 'improvement' in comparison to chronic patients. In acute patients, mean values of pain reduction associated with improvement ranged from 3.63 - 5.00 points (absolute), corresponding to a 56.8% - 78.19% decrease, depending on the assessment time point. In chronic patients, mean values of pain reduction associated with improvement ranged from 1.97 - 3.23 points (absolute), corresponding to a 33.92% - 51.42% decrease, depending on the assessment time point.

Conclusions: The results of the present study provide evidence that pain reduction values associated with significant improvement in low back pain patients are significantly dependent on the patients chronicity as well as on the data assessment time point. Therefore, the concept of a single value for 'minimal clinically important difference' (MCID) should be questioned.

2. List of abbreviations

DC	Doctor of Chiropractic
LBP	Low Back Pain
MCID	Minimum/Minimal Clinically Important Difference
NRS	Numeric Rating Scale for pain
ODI	Oswestry Disability Index
PGIC	Patients Global Impression of Change
SD	Standard Deviation
VAS	Visual Analog Scale for pain
ΔNRS abs.	Absolute NRS change
ΔNRS %	Percentage change of the NRS

3. Introduction

In 1989, Jaeschke et al. [1] defined the minimal clinically important difference (MCID) as "the smallest difference in a score of a domain of interest that patients perceive to be beneficial". Since then, MCIDs have been investigated and calculated for different outcome measures, but so far there is no gold standard in the method of how to determine or calculate the MCID [2]. There is inconsistency and controversy in quantifying how much reduction in pain on the widely used and validated [3 - 6] numeric rating scale (NRS) is clinically meaningful for low back pain patients undergoing various treatments [2]. It has therefore been suggested that the required quantity of change depends on multiple factors such as the underlying condition, the type of treatment, the characteristics of the patients as well as the type of outcome measures or the administered procedures used to assess the improvement [2, 7]. As expected, the MCIDs found in current back pain studies vary significantly [2]. Some studies state that a 2 point reduction on the numeric rating scale is meaningful to the patient [6, 8 - 11]. Other studies have found percentage changes, mostly with values of approximately 30% reduction of the baseline pain score, to be more accurate in order to describe a minimal clinically meaningful change [4, 6, 9 - 11]. Intuitively, a percentage change in pain seems more reasonable as a 2 point pain reduction could range from only 20% to 100% pain reduction depending upon the baseline pain score.

In the present study we analyzed the association between pain reduction on the numeric rating scale and a clinically significant improvement at various treatment outcome time points in low back pain patients who have undergone chiropractic treatment. To determine whether the patients improved, the patients global impression of change (PGIC) scale was used, which has been stated to provide the single best measure of the significance of an improvement from the patients' perspective [12]. The PGIC has been used in other comparable outcome measure studies [11, 13]. Reference values for clinically relevant pain reduction after predefined treatment periods could enable practitioners to identify non-responders earlier and by changing or modifying the applied treatment, better outcomes might be achieved. Also the data will contribute to the ongoing discussion about pain MCIDs in different patient populations.

Therefore, the purposes of this study were to determine:

A) What percentage of pain reduction is associated with clinically relevant improvement in acute and chronic low back pain patients at various treatment outcome time points?
B) How many points reduction on the numeric rating scale is associated with a clinically relevant improvement in acute and chronic low back pain patients?
C) Do acute and chronic patients need the same amount of pain reduction to significantly 'improve'?

4. Methods

This is a secondary analysis from a prospective cohort outcomes study [14] on low back pain patients undergoing chiropractic treatment.

4.1 Setting

Data were collected between May 2010 and May 2014. All of the 260 active members of the Swiss Chiropractic Association were asked to participate in collecting the data for the study. Forty-four Doctors of Chiropractic (DC) practicing in different parts of Switzerland contributed patients to the study. Data on between 5 to 85 patients were collected per participating DC. Thirteen of the DCs contributed 20 or more patients to the study. The chiropractors received written instructions and the study protocol per e-mail. Furthermore, immediately prior to the start of the study, verbal instructions were given to them at the annual postgraduate convention, which is an event with mandatory attendance for Swiss Chiropractic Association members. Workshops about the use of outcome measures in practice were given by one of the authors (B.K.H.). DCs who were interested in participating in the study had to attend these workshops.

4.2 Patients

The recruitment of the patients was done by the participating DCs who were asked to inform all patients meeting the inclusion and exclusion criteria about the study and encourage them to participate. This process was not monitored by the study‘s committee but periodic e-mail reminders were sent to the DCs.

Inclusion criteria

- New LBP patients
- At least 18 years old
- No chiropractic or other manual therapy received within the past 3 months

Exclusion criteria

- Relative or absolute contraindications to chiropractic manipulative treatment including:
- Tumors, inflammatory spondyloarthropathies, infections, severe osteoporosis, acute fractures or Paget‘s disease

4.3 Treatment

As the aim of the study was to investigate the outcomes of routine chiropractic practice, participating DCs were instructed to treat patients just as usual. There was no predetermined treatment number or treatment method and no specific treatment methods were excluded. However, it is known from a ‚Job Analysis Survey‘ in 2009 that Swiss Chiropractors use the "diversified" technique on between 76 and 100% of their patients. Other commonly used techniques and treatment options include mobilization techniques, trigger-point therapy, therapeutic exercises and advice on the activities of daily living [15].

4.4 Outcome Measures

The following outcome measures were used:

The ‚Numeric Rating Scale‘ for pain (NRS): The NRS is an 11-point rating scale ranging from 0 to 10, 0 meaning 'no pain' and 10 meaning 'the worst pain imaginable'. The NRS and the widely used ‚Visual Analog Scale‘ for pain (VAS) have been shown to give almost identical values in the same patients, but the NRS is better suited for telephone follow-up data collection as done in this study [16 - 19].

‚Patients Global Impression of Change‘ questionnaire (PGIC): The PGIC consists of a 7-point verbal scale including responses of much worse (score of 7), worse, slightly worse, no change, slightly better, better, and much better (score of 1) [13]. To determine whether patients improved, the answers were dichotomized into 2 groups. Patients feeling better or much better (scores of 1 or 2) were categorized as 'improved', all other patients were categorized as 'not improved'. Using the dichotomization of the PGIC to determine significant improvement has been found valid, reliable and it has been used exactly the same way in other studies [13, 14, 20 - 22]. The dichotomized PGIC is the primary outcome measure in the study.

Immediately before their first treatment, enrolled patients were given 2 different forms for completion. One of these was the NRS and the other one the Oswestry Disability Index (ODI). The forms were available in German and French as they are the most frequently used languages in Switzerland. Further information was gathered by the DCs including patient sex, age, whether or not the onset of pain was caused by trauma, duration of current complaint, number of previous episodes, presence or absence of radi-

culopathy, presence or absence of referred leg pain, current use of pain medication, work status, marital status, whether the patient smokes, patient's general health status and the working diagnosis. To make sure that all of the DCs used the terms "radiculopathy" and "referred leg pain" the same, it was emphasized that radiculopathy meant the specific signs and symptoms of nerve root compression being different from "referred leg pain" which has no radicular pattern. One week after the first consultation, patients received a short telephone call conducted by trained research assistants unknown to the patient or the referring DCs. In these short interviews, data from the PGIC, NRS and ODI were collected. The same procedure was repeated 1 month and 3 months after the first treatment, irrespective of whether or not the patient still was in chiropractic care.

4.5 Statistics

The Wilcoxon test for matched pairs was used to calculate the changes of the NRS scores from baseline to the various time frames during and after treatment.

The unpaired Student's t-test was used to compare the NRS actual change scores (normally distributed data) and the NRS percentage change scores between 'improved' and 'not improved' patients for each outcome time point. This was done with the whole cohort data as well as with the data of the acute and the chronic patients separately. To compare the scores between acute patients (symptoms < 4 weeks in duration) and chronic patients (symptoms > 3 months in duration), a one-way ANOVA was done. The proportions of 'acute' and 'chronic' patients regarding 'improvement' were calculated and compared for significant differences in proportions using the χ^2 test with two-tailed P values.

Due to the narrow time slots in which the follow-up data was allowed to be gathered, some follow-up data are missing. These patients were nonetheless included in the statistics if data from other outcome time points was available. Patients with pre-treatment NRS < 1 or missing pre-treatment NRS data were excluded in the final statistics.

4.6 Ethics

Ethics approval was obtained from the Orthopaedic University Hospital of Balgrist ethics committee and Canton of Zürich ethics review board (ethics approval number: EK 16/2009). A written informed consent was obtained from all patients.

5. Results

5.1 Patients characteristics

The data of 895 patients matched with the inclusion and exclusion criteria and were therefore included in the final statistics. Of these, 505 (56.4%) were rated as 'acute' (< 4 weeks of symptoms), 274 (30.6%) were rated as 'chronic' (> 12 weeks of symptoms), 103 (11.5%) had symptoms between 4 and 12 weeks and were rated as 'subacute', 13 (1.5%) patients had missing data of the chronicity.

The age ranged from 18 to 85 years with an overall mean of 43.64 ('acute' mean = 42.62; 'chronic' mean = 44.78) and a SD of 14.41 ('acute' SD = 14.19; 'chronic' SD = 14.45).

Pre-Treatment NRS scores included in the final statistics ranged between 1 and 10, with an overall mean of 5.87 ('acute' mean = 6.20; 'chronic' mean = 5.41) and a SD of 2.13 ('acute' SD = 2.08; 'chronic' SD = 2.06). The most frequently reported pre-treatment NRS scores were 7 (16.4%), 5 (13.2%) and 8 (11.8%).

5.2 Overall improvement measured by the PGIC

As acute and chronic patients had different outcomes, the presented data are divided into 'All LBP Patients', 'Acute LBP Patients' and 'Chronic LBP Patients'. The overall outcomes between acute and chronic LBP patients differ notably with a significantly higher percentage of 'acute' patients having improved compared to the 'chronic' patients at all given assessment time points ($p<0.005$; see also chapter 5.6). These percentage values can be seen in Table 1, showing the overall improvement in all the patients as well as in acute and chronic patients separately, measured by the PGIC.

In the 'All LBP Patients' group, at 1 week, 385 patients have improved, 354 have not. At 1 month, 499 have improved versus 198 who have not improved. At 3 months, 438 have improved versus 111 who have not improved.

In the 'Acute LBP Patients' group, at 1 week, 274 of the patients have improved, 140 have not improved. At 1 month, 323 patients have improved and 72 have not improved. At 3 months, 265 have improved versus 35 who have not improved.

In the 'Chronic LBP Patients' group, at 1 week, 73 of the patients have improved, 160 have not improved. At 1 month, 124 have improved, 90 have not improved. At 3 months 125 of the patients have improved and 56 have not improved.
As some follow-up data are missing, the number of patients is inconsistent over time.

Table 1: Overall improvement (PGIC) of all patients, acute & chronic patients

		1 Week	1 Month	3 Months
All LBP Patients	**improved**	52.2%	71.5%	79.7%
	not improved	47.8%	28.5%	20.3%
Acute LBP Patients	**improved**	66.2%	81.8%	88.3%
	not improved	33.8%	18.2%	11.7%
Chronic LBP Patients	**improved**	31.3%	57.9%	69%
	not improved	68.7%	42.1%	31%

5.3 Mean Pain improvement over time

Table 2 shows the mean NRS changes and standard deviations over time in all measured LBP patients, as well as in acute and chronic LBP patients separately.

Table 2: Mean NRS changes after 1 week, 1 month and 3 months

		1 Week Mean (SD)	1 Month Mean (SD)	3 Months Mean (SD)
All	**ΔNRS abs.**	2.09 (2.48)	3.24 (2.74)	3.71 (2.88)
	ΔNRS %	-30.01 (45.46)	-50.04 (45.01)	-55.98 (53.82)
Acute	**ΔNRS abs.**	2.84 (2.47)	4.09 (2.74)	4.61 (2.63)
	ΔNRS %	-42.99 (37.9)	-62.37 (41.32)	-71.29 (34.28)
Chronic	**ΔNRS abs.**	1.08 (2.06)	2.07 (2.20)	2.45 (2.76)
	ΔNRS %	-14.08 (44.48)	-34.58 (38.45)	-34.7 (65.94)

ΔNRS abs. = absolute NRS change. ΔNRS % = percentage change of the NRS. SD = standard deviation.

5.4 Mean NRS changes in all 'improved' and in all 'not improved' patients

Table 3 shows the mean NRS changes and the standard deviations of all LBP patients, depending on the PGIC category ('improved' or 'not improved').

The t-tests showed significantly ($p<0.005$) different NRS changes over time (absolute and percentage) between the 'improved' group and the 'not improved' group at all given assessment time points (1 week, 1 month, 3 months).

Table 3: Mean NRS changes over time in all 'improved' and in all 'not improved' patients

		Mean (SD)	P-Value (ΔNRS in 'improved' vs. ΔNRS in 'not improved' patients)
ΔNRS abs. 1 Week	**improved**	3.21 (2.42)	p<0.005
	not improved	0.84 (1.86)	
ΔNRS % 1 Week	**improved**	-50.47 (36.83)	p<0.005
	not improved	-7.44 (43.25)	
ΔNRS abs. 1 Month	**improved**	4.12 (2.50)	p<0.005
	not improved	1.02 (1.95)	
ΔNRS % 1 Month	**improved**	-65.62 (34.43)	p<0.005
	not improved	-10.72 (44.91)	
ΔNRS abs. 3 Months	**improved**	4.38 (2.56)	p<0.005
	not improved	1.12 (2.53)	
ΔNRS % 3 Months	**improved**	-69.23 (34.70)	p<0.005
	not improved	-4.13 (78.91)	

ΔNRS abs. = absolute NRS change. ΔNRS % = percentage change of the NRS. SD = standard deviation.

5.5 Comparison of acute with chronic patients for the mean NRS changes over time in 'improved' and in 'not improved' patients

Tables 4, 5 and 6 show the mean NRS changes and the standard deviations depending

on the PGIC category ('improved' or 'not improved') and the chronicity category ('acute' or 'chronic').

The t-tests showed significantly ($p<0.005$) different NRS changes over time (absolute and percentage) between the 'improved' group and the 'not improved' group at all given assessment time points (1 week, 1 month, 3 months) in acute patients as well as in chronic patients.

Table 4: Comparison of acute with chronic patients for the mean NRS changes in 'improved' and in 'not improved' patients at 1 week:

		Acute		**Chronic**	
		ΔNRS abs. 1 Week	**ΔNRS % 1 Week**	**ΔNRS abs. 1 Week**	**ΔNRS % 1 Week**
Mean (SD)	**improved**	3.63 (2.32)	-56.80 (30.68)	1.97 (2.26)	-33.92 (42.93)
	not improved	1.21 (1.89)	-15.32 (35.52)	0.67 (1.83)	-5.04 (42.30)
P-Value (ΔNRS in 'improved' vs. ΔNRS in 'not improved')		p<0.005	p<0.005	p<0.005	p<0.005

ΔNRS abs. = absolute NRS change. ΔNRS % = percentage change of the NRS. SD = standard deviation.

Table 5: Comparison of acute with chronic patients for the mean NRS changes in 'improved' and in 'not improved' patients at 1 month:

		Acute		**Chronic**	
		ΔNRS abs. 1 Month	**ΔNRS % 1 Month**	**ΔNRS abs. 1 Month**	**ΔNRS % 1 Month**
Mean (SD)	**improved**	4.74 (2.41)	-72.96 (31.34)	2.77 (2.23)	-49.09 (35.32)
	not improved	1.17 (2.22)	-14.69 (47.18)	1.08 (1.74)	-14.34 (33.43)
P-Value (ΔNRS in 'improved' vs. ΔNRS in 'not improved')		p<0.005	p<0.005	p<0.005	p<0.005

ΔNRS abs. = absolute NRS change. ΔNRS % = percentage change of the NRS. SD = standard deviation.

Table 6: Comparison of acute with chronic patients for the mean NRS changes in 'improved' and in 'not improved' patients at 3 months:

		Acute		Chronic	
		ΔNRS abs. 3 Months	**ΔNRS % 3 Months**	**ΔNRS abs. 3 Months**	**ΔNRS % 3 Months**
Mean (SD)	**improved**	5.00 (2.39)	-78.19 (27.55)	3.23 (2.48)	-51.42 (40.65)
	not improved	1.89 (2.56)	-22.19 (35.87)	0.67 (2.56)	2.60 (91.95)
P-Value (ΔNRS in 'improved' vs. ΔNRS in 'not improved')		p<0.005	p<0.005	p<0.005	p<0.005

ΔNRS abs. = absolute NRS change. ΔNRS % = percentage change of the NRS. SD = standard deviation.

5.6 Comparison of the 'acute' group and the 'chronic' group (one-way ANOVA and χ^2 test)

The ANOVA showed significant (p<0.005) differences between the 'acute' group and the 'chronic' group at all assessment time points (1 week, 1 month, 3 months) in terms of the clinically relevant absolute and percentage NRS changes.

The association between the chronicity ('acute' or 'chronic') and the improvement category ('improved' or 'not improved'), measured by the χ^2 test with two-tailed P values, has been shown to be highly significant (p<0.0001) at all given assessment time points (1 week, 1 month and 3 months).

6. Discussion

6.1 Key Findings

One of the main key findings of the study was that not only do the outcomes of acute and chronic patients significantly differ, but also their mean absolute and percentage NRS changes that are associated with a clinically relevant improvement on the PGIC scale, at all of the assessment time points are different. This strongly suggests that a single NRS value in terms of points or percentage of the NRS reduction equating to clinically relevant 'improvement' is not applicable to all patients undergoing chiropractic treatment for low back pain. What patients consider to be clinically relevant pain reduction differs between acute and chronic patients. This is important for research studies evaluating clinically relevant pain reduction after various treatments. After 1 week for example, the mean NRS change in 'acute' patients that was associated with 'improvement' on the PGIC scale was 3.63 (absolute) which equates to a 56.8% decrease in relation to the pre-NRS score, whereas chronic patients who reported clinically relevant improvement had a mean NRS reduction of 1.97 NRS points (absolute) corresponding to a 33.92% reduction. The clinically relevant values obtained after 1 month and 3 months also differed significantly between the acute and chronic patients, with acute patients always having higher absolute and percentage change values that they deemed clinically relevant compared to the chronic patients.

The mean values obtained of absolute and percentage NRS change in 'improved' patients were always higher than the proposed 2 point reduction on the NRS scale [6, 8 - 11] and the 30% or 33% decrease reported in the literature [4, 6, 9 - 11] as a MCID, with the exception of the absolute NRS change value in the 'chronic' group at 1 week (1.97) which was almost 2 points with a corresponding percentage change of just under 34%. Consistent with previously reported studies was that the obtained mean values in 'not improved' patients were always lower than the proposed MCID values.

6.2 Comparison of results with results of other studies

The mean NRS change values for 'chronic' patients at 1 week (1.97 points absolute, -33.92%) are consistent with the often suggested values of 2 points pain reduction [6, 8 - 11], or 30% to 33% pain reduction [4, 6, 9 - 11].

The values representing clinically relevant 'improvement' found in the 'acute' group were much higher than the proposed MCID values found in the previously mentioned studies that were realized with chronic LBP patients.

However, higher MCID values for acute LBP patients in comparison to chronic LBP patients have been proposed before with absolute NRS change values of 3.5 - 4.7 points in acute patients compared to 2.5 - 4.5 points in chronic patients [23, 24], depending on the methods that have been used to determine the MCID. Our results demonstrated that the MCIDs of acute and chronic patients differ significantly. Therefore, the MCID should not be seen as a fixed value, as it strongly depends on the patient population (more chronic patients will lead to lower MCIDs, more acute patients will lead to higher MCID estimations) and the methods used to determine the MCID [23 - 25]. However, there is little literature found regarding MCIDs in acute LBP patients.

6.3 Strengths and limitations of the study

Strengths:

One of the strengths of the present study is the large number of patients in both the acute and chronic categories providing strong power for the results. An important strength of this study is that the validated Patient's Global Impression of Change (PGIC) scale to determine clinically relevant 'improvement' was used as the primary outcome measure and thus the NRS pain change scores could be compared to this outcome measure [4, 6, 11, 13, 14, 20 - 22]. This gives confidence that the NRS values obtained when determining clinically relevant improvement in the acute and chronic patients are valid and reliable.

Given the fact that 44 doctors of chiropractic in different parts of Switzerland have contributed to the data acquisition, this study provides results derived from the outcomes of typical chiropractic practice in Switzerland. As different therapeutic methods have been used by the participating chiropractic doctors, the study cannot make any conclusions regarding the efficacy of different methods being used to treat low back pain and therefore the results could have turned out differently if the data would have been collected in another country with other therapeutic methods that are commonly used. However, this was not the aim of the study.

Limitations:

In the present study, patients were categorized only into 2 groups: 'acute' and 'chronic'. As there was such a significant difference between these groups, the question is if the patients should have been divided into more chronicity groups, and in general, if different MCIDs should be determined for patients with different chronicities such as acute, subacute, chronic or even for further subcategories. It is possible that depending on the chronicity, patients rate their pain differently. Whereas in acute patients pain could be the most disturbing part of their consulting issue, chronic patients who are used to having pain could suffer more from disabilities or movement restrictions rather than pain or they appreciate smaller changes of their pain levels more than acute patients who expect being pain free after a treatment. The MCID could also depend on how long it takes after the start of treatment until the pain declines. 'Acute' patients with no improvement after 3 months had a mean absolute NRS-change of 1.89 points (respectively -22.19%). Considering the standard deviation (2.56 points, 35.87%), there were patients with more than 2 points or 30% of NRS decrease that still felt 'not improved' while others already reported improvement at lower NRS-change levels. One possible explanation is that the MCID rises simultaneously with the amount of elapsed time since the beginning of the treatment because the change is slower and therefore less noticeable. Another plausible explanation of these values is that the patients feel 'not improved' despite having less pain. This could be due to unfavorable psychological or social situations/conditions, movement restrictions or disabilities. In such cases the biopsychosocial model [26] should be used for a prognosis concerning 'improvement' rather than looking at pain as a single contributing factor for the well-being of a patient.

In this study the association between a decrease on the NRS and an improvement on the PGIC scale was studied. Mean values were analyzed at different assessment time points. These mean values do not necessarily represent the same as a MCID. After 1 month and 3 months the mean absolute and percentage values associated with an improvement on the PGIC scale increased over time. The most likely explanation for this is that patients having already improved were still continuing to improve after the first week, which had an influence on the subsequently measured mean values. Therefore, to determine the MCID by using the NRS compared to the PGIC, early reports of improvement should be used. The NRS change should be measured as soon as possible after the individual change from 'not improved' to 'improved', so further improvement

would not have an effect on the reported NRS change leading to an 'improved' on the PGIC scale and therefore would not have an effect on the estimated MCID value.

6.4 Conclusion

The results of this study indicate that the MCID depends strongly on the chronicity of the patients as well as on the data assessment time points, and therefore single values as minimally clinically important pain reductions are not appropriate for all patients.

To obtain NRS change values most close to the MCID, patients should be surveyed as soon as possible after treatment.

As the PGIC provides an outcome measure for the overall improvement of a patient, regardless of the cause leading to the improvement, there are many factors that can contribute to a change from 'not improved' to 'improved' and the pain measured by the NRS should not be isolated and considered to play the decisive role leading to the change. A change on the PGIC scale can be seen as the result of an overall-improvement of the patients biopsychosocial condition.

6.5 Remaining uncertainties

As the results of NRS changes associated with an improvement on the PGIC scale vary significantly depending on the chronicity and the elapsed time between treatment start and the data gathering, the question arises whether or not different MCIDs should be applied in different patient subgroups.

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9. Lebenslauf

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10. Erklärung

Masterarbeit

Ich erkläre ausdrücklich, dass es sich bei der von mir im Rahmen des Studiengangs eingereichten schriftlichen Arbeit mit dem Titel

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* Falls die Masterarbeit eine Publikation enthält, bei der ich Erst- oder Koautor/-in bin, wird meine eigene Arbeitsleistung im Begleittext detailliert und strukturiert beschrieben.